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Remarks/Arguments

By way of the present amendment, Applicants have canceled Claims 10-27. The subject matter of canceled Claims 10-27, is being pursued in Applicants' pending U.S. Application Serial No. 11,051,779, filed February 04, 2005.

Nine (9) claims remain pending in the application: Claims 1-9, of which Claim 1 is independent. Applicants respectfully request reconsideration of the Nine (9) pending claims in view of the comments below.

Claim Rejections - 35 U.S.C. § 102

Claims 1-3, and 8 were rejected under 35 U.S.C 102(b) as being anticipated by Baudino et al. (U.S. Patent 5,927,227). Claims 1-3, and 8 were also rejected under 35 U.S.C 102(e) as being anticipated by Baudino (U.S. Patent 6,044,304). Applicant respectfully traverses the 102(b) and 102(e) rejections.

In the first Office Action, mailed 01/12/2005, the Examiner indicated that Claims 1-9 were allowed. In making this allowance, the Examiner was apparently convinced that the burr hole ring shown in Baudino et al., which has a flange which protrudes above the skull, and is thus not "flush" with the skull as required by Claim 1, was not shown or suggested by Baudino et al. However, in the second Office Action, mailed 05/11/2005, the Examiner gave "flush" its broadest meaning of directly abutting or immediately adjacent, and using this broad meaning rejected the claims. Applicants respectfully submit that giving "flush" such a broad meaning is in error, and goes against the teaching of the specification and current case law.

In the recent decision Phillips v. AWH Corp., 2005 U.S. App. LEXIS 13954, *48 (Fed. Cir., 2005), the court dealt with this very issue of claim construction, and whether a claim term should be given its broadest meaning, such as a dictionary definition, or whether the claim term should be construed in accordance with the teachings of the specification. The court stated:

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Assigning such a limited role to the specification, and in particular requiring that any definition of claim language in the specification be express, it is inconsistent with our rulings that the specification is "the single best guide to the meaning of a disputed term," and that the specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."

On page 3 of the Office Action, The Examiner has interpreted the term "flush" in Claim 1 as "its broadest meaning of directly abutting or immediately adjacent." In Applicants' specification, a more specific definition for the term "flush" has been defined as a feature of a cranial sealing plug assembly that avoids unsightly flange protrusions which may cause skin erosion with the patient's skull. Accordingly, the following sections of Applicants' specification arguably support a more specific definition for the term "flush".

Page 6, paragraph [0012] "*Despite the various types of burr hole plugs known in the art, as illustrated by the examples cited above, significant improvements are still possible and desirable, particularly relative to a burr hole plug assembly that: ... (e) is flush with the skull to avoid skin erosion and to eliminate any unsightly flange protrusion from the patients' skull (which can be especially important in the population of older balding males)... "*

Page 7, paragraph [0015] "*The invention disclosed and claimed herein provides various embodiments of cranial sealing burr hole plug assemblies. Such assemblies accommodate various burr hole sizes, provide various lead positioning features, are adjustable and compressible, provide a design that is flush with the skull...*"

Page 7, paragraph [0016], "*In accordance with one aspect of the invention, there is provided a compressible burr hole plug assembly that can be inserted into a variety of burr hole sizes and provides a radial force for positioning the lead.*

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Advantageously, such embodiment is flush with the patient's skull and avoids unsightly flange protrusions which may cause skin erosion."

Page 12, paragraph [0055], "the reaction force F2 eliminates the need for ridges on the outer diameter of the plug ring 10, and further eliminates the need for a flange above the skull that acts to limit the motion in the X, Y, and Z directions 21, stabilizing the burr hole plug assembly in the burr hole."

In contrast, the Baudino et al. prior art patent '227 specifies an upper flange portion (10). See column 3 lines 14-16 and Figures 1-11. The prior art patent '304 also specifies an upper flange portion (12). See column 4 lines 24-26 and Figures 1-4. Applicants' have distinguished the prior art as having a protruding flange and creates an unsightly bump in the head. See, e.g., the following section of the specification:

Page 12, paragraph [0056] "A prior art embodiment of a burr hole assembly 13 with ridges 4, a flange 6 and septum material 8 in central hole 11 is shown in FIG 12. As is evident from FIG. 12, the flange 6 would protrude above the patients' skull when the ridge section 4' is inserted in the burr hole. Disadvantageously, a protruding flange 6 may cause skin erosion, and creates an unsightly bump in the head, especially in the patient population of older balding males."

In view of the above observations, it is clear that "flush" as used in Claim 1 has a narrower meaning than has been applied by the Examiner. Accordingly, it is respectfully submitted that the rejection of independent Claim 1 under 35 U.S.C 102(b) as being anticipated by Baudino et al. (U.S. Patent 6,927,227) and under 35 U.S.C 102(e) as being anticipated by Baudino (U.S. Patent 6,044,304), have been overcome and thus should be allowable. Claims 2, 3, and 8 are dependent claims that depend from Claim 1, and thus should also be allowable.

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Claim Rejections - 35 U.S.C. § 103

Claims 4-7 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino et al. (U.S. Patent 5,927,227) in view of Baudino (U.S. Patent 6,044,304). Claims 4-7 and 9 are dependent claims that depend from Claim 1, and thus should be allowable for the same reasons that Claim 1 is allowable. Furthermore, Applicants submit that the invention set forth in Claim 1 is not shown or suggested by the teachings of Baudino et al. This is because Baudino et al. does not suggest that the burr hole ring (10) be flush with the skull, but rather expressly teaches, as pointed out above, that there be an upper flange portion (12) that protrudes above the patient's skull, which is contrary to the teachings of the specification that the plug be flush with the skull without unsightly flange protrusions.

In view of the above, the claimed invention as a whole, as presented by original independent Claim 1, would not have been obvious to one of ordinary skill in the art at the time the invention was made. As specified in the specification, Applicants have disclosed "a cranial sealing plug assembly adapted for insertion into a burr hole that is "flush" with the patient's skull". The term "flush" is defined as avoiding unsightly flange protrusions as described above.

If the Examiner rejects Claim 1 in the next Office Action, Applicants' would be willing to amend Claim 1 to include a wherein clause which specifically states that the cranial sealing plug assembly have no protrusions or flanges that extend above the surface of the skull. However, in view of the recent Phillips decision, and the explicit statements made in the specification and in this response that "flush" means not having flange protrusion, Applicants believe such further amendment of Claim 1 should not be needed.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and that the pending claims are in condition for allowance. An indication of allowability of original Claims 1-9 at an early date is thus earnestly solicited.

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The Examiner is invited to telephone the undersigned, Victoria A. Poissant, should any issues remain after consideration of this response, in order to permit early resolution of such issues.

Respectfully Submitted,



Victoria A. Poissant
Reg. No. 56,871

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Address all correspondence to:

Bryant R. Gold, Reg. No. 29,715
Advanced Bionics Corporation
25129 Rye Canyon Rd.
Valencia, CA 91355
Fax: (661) 362-1507

Address all telephone inquiries to:

Victoria A. Poissant, Reg. No. 56,871
Phone: (661) 362-1923

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